DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–1031 and 00M–1032]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; List of Premarket Approval Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the Internet at http:// www.fda.gov/cber/appr1999/1999approv.htm. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document, when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials

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by posting them on FDA's home page on the Internet at http://www.fda.gov, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant: in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of the PMA applications reviewed within CBER, for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through September 30, 1999. There were no denial actions during this period. The list is in order by PMA number and provides the manufacturer's name, the generic name or trade name, and the approval date.

TABLE 1.—LIST OF APPROVAL PMA'S FROM JULY 2, 1999, THROUGH SEPTEMBER 30, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
BP 97–0001/01/00M–1031	Nexell Therapeutics, Inc.	Isolex 300 Magnetic Cell Selection System and Isolex 300i Magnetic Cell Selection System	July 2, 1999
BP 97–0003/00M–1032	Dendreon Corp.	DACS™SC	July 23, 1999

Dated: 3/23/00

March 23, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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